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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/550,661 | 09/26/2005 | William Brown | 101025-1P US | 3049 |
| 22466 7590 08/14/2008 ASTRA ZENECA PHARMACEUTICALS LP GLOBAL INTELLECTUAL PROPERTY 1800 CONCORD PIKE WILMINGTON, DE 19850-5437 | | | EXAMINER COVINGTON, RAYMOND K | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1625 | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/550,661

Applicant(s)

BROWN ET AL.

Examiner

Raymond Covington

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 1/9/06
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 7-11, 13 and 14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for pyrrole, thiazole, piperidine and pyridine, it does not reasonably provide enablement for the broader scope in claim 1 and claims dependent thereon. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. Specification provides no guidance as to what other rings might be suitable and there is no basis in the prior art directed to similar compounds having the same activity as herein.

Scope of 3- to 8-membered mono or polycyclic heterocyclics having 1 to 4 heteroatoms is not adequately enabled. A review of the specification shows only 1 ring analogs described that are representative of actual working examples.

The limited data provides no clear evaluation of how the remaining scope with up to 4 hetero atoms in any array and degree of unsaturation might affect potency to a large or small degree.

Applicants have failed to establish that the compounds are structurally and functionally similar to those tested herein or to known compounds having the same activities.

There is thus no reasonable basis for assuming that the myriad of compounds embraced by the claims will all share the same physiological properties since they are so structurally dissimilar as to be chemically non-equivalent. Note In re Surrey 151 USPQ 724 regarding sufficiency of disclosure for a Markush group. Also see MPEP 2164.03 for enablement requirements in cases directed to structure- sensitive arts such as the pharmaceutical art. Also note the criteria for enablement as set out in In re Wands cited in MPEP 2164.01(a), August 2000 edition. Thus given the breadth of the claims, the level of unpredictability in the art and the lack of direction (i.e. working examples) provided as to what other ring systems might work this rejection is applied.

Though clearly one of ordinary skill in the art could identify much of what is within the scope of the R7 and R4 the delineation between what is and what is not claimed has not been circumscribed. That is, all of what is claimed is not identifiable. The specification only provides some examples of what these terms may signify, but does not limit "heterocyclic" or "heteroaryl" to any particular definition. For example, pages 5-7 teach many examples of heterocyclic groups,

but this section is prefaced with “includes, for example” so it is clear that applicants do not wish to be limited to only those named heterocycles. Again, where the delineation between claimed subject matter and unclaimed subject matter lies is unclear from a reading of the claims in light of the specification. More than one definition of the general term “heterocyclic” or “heterocycle” is accepted by those of ordinary skill in the art of organic chemistry. Some consider cyclic organic compounds wherein at least one carbon atom is replaced by sulfur, oxygen or nitrogen to be heterocyclic compounds, while others of ordinary skill include selenium, tellurium, boron or tin containing rings to be within the scope of the term “heterocyclic” as it is commonly used, and some definitions of “heterocyclic” do not require carbon to present at all.

The examiner directs applicants' attention to the following three references:

On page 282 of the McGraw--Hill Dictionary of Chemical Terms(1990), the definition of “heterocyclic compound” is a compound in which the ring structure is a combination of more than one kind of atom. On page 490 of the Concise Encyclopedia Chemistry (1993), the definition of “heterocycles” is cyclic hydrocarbon compounds in which the ring consists of carbon and at least one other element, usually, N, O or S. The definition goes on to explain that the possibilities for synthesis are nearly unlimited, and that compounds wherein the heteroatoms

are of elements like phosphorous, arsenic, selenium, and tellurium are being incorporated with increasing frequency. On page 594 of Hawley's Condensed Chemical Dictionary (1993), "heterocyclic" is defined as a closed-ring structure, usually, either 5 or 6 members, in which one or more of the atoms in the ring is an element other than carbon, e.g, sulfur, nitrogen, etc. These three definitions should make it abundantly clear that there is no one specific and exact definition of the word "heterocyclic," thus when this term is present as a claim limitation, the metes and bounds of protection are not pointed out and distinctly claimed. Though the three above-cited definitions of the term have some shared aspects, chemists of ordinary skill would not necessarily agree on the full scope and meaning of the term "heterocyclic."

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5 and 7-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Delorme et al US 6187792 or Delorme WO 98/28275.

Delorme et al US 6187792 and Delorme WO 98/28275 both teach diphenyl piperidinylidene methyl compounds corresponding to those recited in the claims for use in treating pain. See, respectively, column 2 lines 1+, columns 3-4, note in particular definitions A and column 5 note in particular definitions B, and, pages 4-5. Selection of these common analogous substituents would have been obvious to one of ordinary skill in the art as the resulting products would not have been unexpected.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond Covington whose telephone number is (571) 272-0681. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres at telephone number (571) 272-0867.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR

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only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/R. C./
Examiner, Art Unit 1625

/Janet L. Andres/
Supervisory Patent Examiner,
Art Unit 1625

RKC